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Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

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Subject: **Comments regarding FDA Proposed Rule, Docket No. 97N-0023**

Because my eleven year old son, Thomas Jr., has severe asthma, I have a significant interest in the FDA's Proposed Rule (Docket No. 97N-0023) that will begin phasing out CFC-based Metered Dose Inhalers (MDIs) originally proposed in a 1997 ANPRM. Tommy currently has a very successful asthma management program This program, which is consistent with the National Institute of Health's ***"Guidelines for the Diagnosis & Management of Asthma,"*** NIH Publication No. 97-405 1, July 1997, is dependant on the regular use of CFC-based MDIs. While the MDI medications included in the program have changed over time, Tommy is presently using three different CFC-based MDIs: Intal, Flovent, and Proventil. It is from this very personal perspective and the experience that I have had over the past nine plus years managing Tommy's asthma, that I offer the following comments on the proposed rule.

- I agree with the FDA's decision to use a decision process based on a moiety-by-moiety approach, rather than the therapeutic class approach suggested in the ANPRM.
- The criteria that the FDA should use to determine whether or not a subpopulation is significant is very simple: **EVERY SUBPOPULATION** IS **SIGNIFICANT!** Using any other criteria would suggest that someone or some small group could be viewed as "insignificant," and I am not willing to accept this potential categorization for my son. Furthermore, I am fairly confident that the FDA will not be able to identify any asthmatic willing to be classified as part of an "insignificant" subpopulation."
- I am concerned that the "Listing of Active Moieties" (Section II.F) does not appear to be all inclusive. Some drug substances currently available, (e.g., Cromolyn found in the Intal product that my son currently uses), are neither a MDI steriod nor a MDI adrenergic bronchodilator. In addition, a number of currently available drug substances listed in Table 1 of this proposed rule appear to have been excluded from the proposed "reorganized list" referenced in "2 1 CFR part 2" Section 2.125(e). **All FDA-approved and currently available asthma-related MDI drug products should be granted a "grandfathered" essential use designation** and included in the list.
- Because an asthma attack can be a life threatening experience, the FDA must adopt a conservative approach to making all decisions to remove the essential use status of any current MDI product. The safest approach from the perspective of all people afflicted with asthma would be to **wait until a product is no longer marketed before initiating proceedings to remove the essential use status.** This would comply with the spirit of a CFC-free environment because, although a product would still have the essential use designation, it would not be adversely impacting the environment because no one would be using it.
- **There must be a fail-safe process for collecting and evaluating postmarketing information related to the adequacy of current MDI alternatives.** Inadequacies inherent in the current drug approval process and the FDA's MEDWATCH program have recently been demonstrated by a host of newsworthy tragedies such as the "fen-phen" diet pill fiasco. In addition, the **FDA must establish a procedure that will quickly re-instate the essential use status and guarantee availability of a "retired" CFC-based MDI should the FDA-approved replacement be removed-from or forced-off the market** under circumstances similar to the drugs in the "fen-phen" scenario.

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- In addition to grandfathering all existing CFC-based MDIs (as I suggest above), the proposed **rule should have a grandfathering provision related to the term change (i.e., ODS versus CFC) in Section II.B.** If, as stated in the proposed rule, the term change "will not have any substantive effect on FDA regulated products in use today," a grandfathering provision would serve the very useful purpose of ensuring the continued availability of all current FDA-approved drugs without having any substantive negative effect on the quality of the environment.
- **Section II K proposes January 1, 2005 as a date for presuming that sufficient alternative products are available** to remove the essential use designation for all CFC-based MDIs for which the moiety has not been reformulated. **I feel the proposal of any such date to be unacceptable** because
    1. This proposal does not explicitly state the criteria that is to be used to conclude that a new non-CFC-based product can be used by all people with asthma instead of the CFC-based product whose moiety has not been reformulated, and
    2. This proposal does not provide any insight as to the qualifications of the "advisory committee" that the FDA will consult with to make such a decision.

  For this proposed rule making to include wording along the lines suggested in the text, the **FDA must first add explicit details regarding the process and judging criteria** that will used to determine that a non-CFC-based product provides the same or better medical coverage than the CFC-based moiety that will be removed from the essential use list without having been reformulated. In addition the **FDA must state clearly the qualifications of personnel that will make up the "advisory committee"** for such a decision. At a minimum the committee should include members of the expert panel assembled by the National Institute of Health for the then most current issue of ***"Guidelines for the Diagnosis & Management of Asthma,"*** and professionals in the medical field selected/sponsored by members of the House Committee on Commerce's subcommittee on Health & Environment.
- I am disturbed by the way that **the FDA has dismissed a number of comments to *the* ANPRM** as being, to paraphrase, "outside the domain of the FDA's authority," or as being, to paraphrase, "irrelevant because of a mandate to ban or eliminate CFC-based MDIs." I believe that **the FDA needs to directly address each comment so dismissed.** The comments should be revisited and judged solely on the merits of the comment content rather than be ignored or side-stepped. If a comment seems reasonable except for the fact that the FDA lacks the authority to act it out, FDA personnel should take a proactive approach to alerting the proper government agency as to the suggested action (or, alternatively, petition Congress to grant the necessary authority to the FDA). If a comment sheds light on a shortcoming of the Montreal Protocol agreement, the FDA should take the steps necessary to ensure the continued welfare of United States citizens using CFC-based MDIs.

In closing, I mention that I am asking my eleven year old son, Tommy, to also provide comment on the proposed rule. Although he is only a young boy, he does understand that the MDIs he uses today play a significant role in his being able to attend school on a daily basis and to vigorously participate in all the activities that he enjoys. Please write the proposed rule as if Tommy were your son, and you were trying to ensure that he would have, on a going forward basis, all the medication he could possibly need to properly control his asthma as he continues to grow up and enjoy life.

Thomas R. Farese

copy to:
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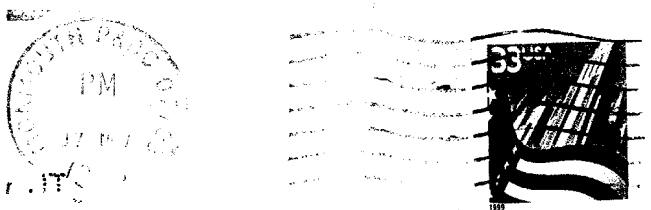

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